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April 28, 2022

VIA ECF

Special Master
Hon. Thomas Vanaskie
Stevens & Lee
1500 Market Street, East Tower, 18th
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Philadelphia, PA 19103
TIV@stevenslee.com

RE: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No.
1:19-md-2875-RBK-KMW (D.N.J.)

Dear Judge Vanaskie:

I write on behalf of the Defendants' Executive Committee to provide Defendants' position with respect to the agenda topics for the conference with the Court on April 29, 2022. Defendants do not expect the need to discuss any confidential materials as part of these agenda items, but reserve the right to move to a confidential setting should the need arise.

1. Status of Defendants' Motion to Compel Testing Documents from Ron Najafi

On Monday, April 25, Plaintiffs filed their response to Defendants' Motion to Compel. Accordingly, the Motion is now ripe for adjudication. With respect to the substance of Plaintiffs' response, Defendants respectfully seek to clarify several points.

First, Plaintiffs' assertion that Defendants have been inconsistent with respect to the documents being sought from Dr. Najafi is incorrect. The Court need only compare Defendants' list of requests set forth in the initial meet-and-confer

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letter, [ECF No. 1984-2](#), with the list of requests in the resultant Motion to Compel, [ECF No. 2013](#), to see that they are verbatim the same.

Second, Plaintiffs' characterization of the meet-and-confer process is also inaccurate. In accordance with the Court's instructions, Defendants made a good-faith attempt to narrow the issues through the lengthy meet-and-confer process, but the parties were unable to reach a compromise that was acceptable to both sides. Despite initial denials, Plaintiffs now admit that Dr. Najafi did, indeed, conduct testing at the behest of Valisure for purposes of corroborating the nitrosamine levels set forth in the Citizen Petition. Thus, at a minimum, we know that Dr. Najafi is in possession of (i) correspondence with Valisure regarding the testing; (ii) Valisure's test results; (iii) product from Valisure; (iv) documents reflecting chain of custody from Valisure to Emery; (v) documents reflecting Emery's methods, processes, and controls; (vi) Emery's testing data; and (vii) correspondence from Emery to Valisure conveying the results of Emery's testing. All of this is relevant and discoverable. Nonetheless, Plaintiffs were not willing to produce **any** documents. Their last and final offer during the meet and confer was to provide an attorney certification that the levels of NDMA and DMF detected by Dr. Najafi's lab on samples provided by Valisure were not within some unspecified margin of error as compared to the levels of NDMA and DMF detected by Valisure in samples of Novartis and Aurobindo product. For reasons explained in Defendants' motion, this compromise is unacceptable to Defendants and falls far short of what Defendants are entitled to discover under the law. Accordingly, before Defendants filed their Motion to Compel, counsel for Defendants informed Mr. Slater by phone that Defendants did not believe a compromise was within reach and, therefore, Defendants intended to press forward with the motion. Plaintiffs' counsel did not disagree that the parties had reached an impasse. As such, it is inaccurate for Plaintiffs to suggest that Defendants never "responded" to Plaintiffs' final offer.

Third, Plaintiffs continue to cling to arguments raised during the meet and confer that are easily refuted. For example:

- Plaintiffs rely on the notion that Dr. Najafi's testing was "blinded." As explained in the Motion to Compel, the manufacturer of a tablet can be identified through simple, visual inspection. Certainly Dr. Najafi is aware of this; thus, to the extent he claims not to be aware of the manufacturer of the tablets he tested, his ignorance can only be described as willful.

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- Plaintiffs have no answer to Defendants' explanation for why it can reasonably be inferred that the testing performed by Valisure (and, perhaps, Dr. Najafi) was indeed Novartis's brand-name, FDA-approved product. Plaintiffs' suggestion that it is irrelevant whether NDMA was present in Novartis's RLD product is similarly nonsensical. Indeed, the central premise of Dr. Najafi's opinion is that generic valsartan was not the "same as" the brand-name product because of the presence of nitrosamine impurities. Defendants believe this opinion is unreliable and contrary to science and law, but if NDMA has been detected in the RLD, Dr. Najafi's opinions collapse, even under his own flawed approach.
- Plaintiffs speculate that, perhaps, there was some flaw in the methodology used by Valisure to quantify NDMA. This conjecture apparently is the brainchild of Plaintiffs' attorneys, not their expert, as there is no citation to support any of their postulations. In any event, Plaintiffs' conjecture is self-defeating, given Dr. Najafi's testimony that the levels detected by his lab were comparable to the levels detected by Valisure. Moreover, the existence of open questions regarding the reliability of the methods used by Valisure—and, by extension, Emery—weighs in favor of **compelling** the production of the underlying documents, not **suppressing** them.
- The fact that Diovan or Exforge has not been recalled is also a red herring. Only products that exceed FDA's conservative AI limit of 96 ng/day for NDMA will be recalled. Accordingly, the mere fact that the RLD was never recalled does not mean NDMA was not detected. Notably, Dr. Najafi's own opinion does not rest on whether product was recalled. Indeed, according to Dr. Najafi, the **level** of NDMA is irrelevant. His opinion is based on the presumption that the level of NDMA and NDEA in the brand-name products was **zero**; thus, any detectable level of NDMA found in those products undermines Dr. Najafi's opinions—rendering the information relevant and discoverable.
- The fact that Valisure was not retained by Plaintiffs in this MDL proceeding is, again, immaterial. Valisure sent Dr. Najafi product, testing data, and other correspondence related to valsartan. Whether Defendants intend to seek third-party discovery from Valisure at some later time does not excuse Plaintiffs' obligation to produce relevant,

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discoverable documents within their experts' possession, custody, and control.

- Plaintiffs describe Defendants' requests as a "fishing expedition," even though their own expert testified under oath that he has in his possession testing data from both his lab and Valisure regarding the potential presence of nitrosamine impurities in VCDs marketed in the United States. This information strikes at the very heart of Plaintiffs' Motion for Class Certification, and Dr. Najafi's opinions in support of that Motion. Plaintiffs' suggestion that the production of protocols and other information is "irrelevant and burdensome"—just a few pages after they put at issue the methods used to generate the data Dr. Najafi possesses—is absurd.
- Plaintiffs suggest that the testing and other documents within their control should be submitted for *in camera* review due to the supposed "confidentiality" of the materials. With regard to discovery sought from Defendants, Plaintiffs have repeatedly argued that production is appropriate in light of the Protective Order entered in this case. Indeed, Defendants have been required to rely upon the Protective Order when producing millions of pages of proprietary information over the course of discovery. Plaintiffs have demonstrated no compelling reason why they should be excused from this obligation.
- Moreover, the process proposed by Plaintiffs whereby the Court would review Emery's testing data ostensibly to compare it to the levels detected by Valisure in Novartis's product and, on that limited basis, determine relevance, is woefully inadequate. First, as established, any testing performed by Emery and Valisure on VCDs is relevant and discoverable, not just testing performed on Novartis product. Valisure's testing included VCDs from the brand-name manufacturer, multiple Defendants, and several additional generic manufacturers whose products Plaintiffs themselves purchased and ingested. The documents are relevant to both causation and class certification. Second, whether Dr. Najafi's levels happen to correlate to the data set forth in the citizen petition is immaterial to the separate issue of discoverability. This is especially so given Plaintiffs' newly formed position that Valisure's data are unreliable. Plaintiffs cannot have it both ways. Either their expert testified truthfully that his lab was able to "corroborate" Valisure's data, which tends to support the

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notion that there was, in fact, NDMA in the RLD product, or Valisure's methods were flawed, which would mean the correlation between Dr. Najafi's data and Valisure's data tells us nothing about which manufacturer's product Emery actually tested.

Nearly all of the arguments raised by Plaintiffs in their response to Defendants' Motion reinforce the fact that Defendants are entitled to discovery on this important issue. Ultimately, the documents will tell the story, and Defendants should have the opportunity to review them.

Defendants will be prepared to address any issues regarding the Motion to Compel at the CMC.

2. Status Update on the Meet and Confers Regarding Defendants' Indemnification and Defense Agreements

This issue was first raised with the Court at the February 2, 2022 Case Management Conference. *See* Defendants' 2/1/22 Position Statement, [ECF No. 1897](#). At that time, Defendants indicated their willingness to meet and confer with Plaintiffs regarding indemnification agreements. On March 17, 2022, Plaintiffs sent Defendants a letter requesting specific information from each tier of Defendants. (*See* Letter from G. Williamson to S. Goldberg, attached as Ex. A.) In early April, Defendants began to conduct meet-and-confer discussions with Plaintiffs on an individual basis. *See* Defendants' 4/12/22 Position Statement, [ECF No. 2007](#).

This issue was further discussed at the April 13, 2022 status conference, after which Judge Vanaskie issued Special Master Order No. 64, [ECF No. 2015](#). Defendants have continued to conduct individual meet-and-confer discussions with Plaintiffs. The following is an update on the status of these meet and confer discussions between Plaintiffs and specific Defendants.

a) ZHP

Counsel for the ZHP Defendants met and conferred with Plaintiffs' counsel by telephone on April 12 and 22 regarding requests directed to the ZHP Defendants in Plaintiffs' March 17 letter. On April 24, Plaintiffs sent follow-up correspondence asking for written confirmation of certain information and also requesting documents. On April 27, the ZHP Defendants provided the requested written confirmation and agreed to produce certain of the documents requested. On April 28, Plaintiffs wrote to request clarification on two issues, which the ZHP Defendants are investigating and will address with Plaintiffs shortly.

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b) Teva

As discussed at the April mid-month status conference with Judge Vanaskie, counsel for Teva met and conferred with Plaintiffs' counsel on the requests directed to Teva in Plaintiffs' March 17, 2022 letter regarding indemnification agreements on April 8, 2022. Based on those discussions, and as confirmed by Plaintiffs' counsel, there are no outstanding issues with respect to Teva's indemnification agreement information (04/13/2022 Hrg. Tr., 6:9-17).

c) Mylan

Mylan has met and conferred with Plaintiffs and has provided updated information in accordance with SMO 64. The parties agree that there are no issues ripe for the Court's consideration at this time.

d) Aurobindo

Aurobindo met and conferred with Plaintiffs on April 22. Aurobindo understands that Plaintiffs were satisfied with the information provided during the discussion.

e) Torrent

Torrent met and conferred with Plaintiffs on April 18th, and provided an update on April 28th. Torrent continues to gather additional information.

f) Hetero/Camber

Hetero and Camber had a meet and confer with Plaintiffs on April 18, 2022 pursuant to SMO 64. These Defendants have agreed to provide updated information and clarification to Plaintiffs to the extent reasonably necessary.

g) Wholesaler Defendants

Wholesaler Defendants conducted a meet and confer with Plaintiffs' counsel on April 19, 2022. During that call, Plaintiffs' counsel notified Wholesaler Defendants' counsel that, in addition to supplementation of Wholesaler Defendants' prior discovery responses regarding indemnification agreements, Plaintiffs seek disclosure of additional information about indemnification and defense agreements that was not within the scope of the discovery taken from Wholesaler Defendants during the discovery period, which closed on October 4, 2021. The additional

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information requested by Plaintiffs' counsel includes disclosure of whether any entity has assumed any Wholesaler's defense and/or has agreed to reimburse any Wholesaler's costs of defense; if so, whether reimbursements have been made and in what amount; and communications and/or disputes about defense or indemnification, both upstream and downstream. This information is not relevant to the issues in the pending litigation or to settlement. It also is subject to privileges that protect it from disclosure. Wholesaler Defendants remain agreeable to engaging in the meet-and-confer process with Plaintiffs' counsel, but believe clarification of Special Master Order No. 64 is necessary before attempting to do so.

h) Retail Pharmacy Defendants

Counsel for Retail Pharmacy Defendants Albertson's, CVS, Express Scripts, Humana Pharmacy, Kroger, Rite Aid, Walgreens, and Walmart have met and conferred with Plaintiffs' counsel. Optum's meet and confer is scheduled to occur tomorrow (April 29, 2022). Retailer Liaison Counsel is informed that there are no issues ripe for the Court's consideration with respect to those discussions at this time.

3. Holding the Clarification Motions Regarding General Causation in Abevance

The parties have engaged in a meet and confer to discuss the framework for a potential compromise regarding Defendants' pending Motion for Clarification. Specifically, the parties discussed the possibility of deferring this issue in the short term, to be re-raised in connection with the Rule 56 stage in the MDL, and prior to any remand. Plaintiffs have indicated that this framework would be acceptable to them. Defendants are discussing the matter internally and have not reached a final decision point regarding whether to defer the Motion.

4. Reply Brief Deadline to Rule 702 Motions

The current scheduling order, CMO 24, [ECF No. 1930](#), does not include a deadline for the parties to file replies to responses to motions regarding class certification experts. This appears to be an accidental oversight, as a reply deadline was included in prior scheduling orders. See [ECF No. 863](#). Based on the operative response brief deadline of May 25, 2022, Defendants believe the appropriate reply brief deadline for these motions would have been June 8, 2022.

On Wednesday, April 27, the Court granted Plaintiffs' request for an extension of the deadline to submit *Daubert* briefs with respect to the class

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certification experts until Tuesday, May 3, 2022. ECF No. 2025 (text order). (The order erroneously said Tuesday May 4.) Plaintiffs have also committed to responding to the Motion to Exclude Plaintiffs' expert Edward Kaplan, M.D., within the original timeframe contemplated by CMO 24 because Defendants filed that motion before Plaintiffs sought the extension. (*See* 4/26/2022 A. Slater email to Judge Kugler, attached as Ex. B.) Plaintiffs' counsel confirmed that they agree with adding a reply brief deadline and with the below-proposed deadlines, adding one additional day for submitting response briefs due to the Memorial Day holiday. (*See* 4/28/2022 C. Geddis email to S. Harkins, attached as Ex. C.) Accordingly, Defendants propose that the following revised scheduling order be entered:

- Tuesday, May 3, 2022 - Deadline to file *Daubert* motions regarding class certification experts
- Wednesday, May 25, 2022 - Deadline for Plaintiffs to file response to *Daubert* motion regarding class certification expert Edward Kaplan, M.D.
- Thursday, June 2, 2022 - Deadline to file responses to *Daubert* motions regarding class certification experts
- Wednesday, June 8, 2022 - Deadline for Defendants to file replies to responses to Defendants' *Daubert* motion regarding class certification expert Edward Kaplan, M.D.
- Thursday, June 16, 2022 - Deadline to file replies to responses to *Daubert* motions regarding class certification experts

Defendants also raised a potential modification to the deadlines for meeting and conferring and preparing the motion to seal required by local rules in connection with the class certification briefing. Rather than prepare such a motion at the conclusion of the class certification briefing, due to the substantial overlap between exhibits and material cited in the class expert *Daubert* briefs, Defendants proposed, and Plaintiffs' counsel agreed, that the deadlines for meeting and conferring and drafting the motion to seal could run from the conclusion of the *Daubert* briefing on June 16, 2022. (*See id.*) The parties stand ready to prepare an order reflecting the above deadlines and confirming that "end of briefing" for purposes of the motion to seal shall run from the conclusion of the *Daubert* briefing, subject to the Court's approval.

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5. PFS Deficiency Issues

a) Prior Show Cause Orders

The Court issued nine show cause orders returnable at the April 29, 2022 Case Management Conference:

1. *William Byrnes v. Aurobindo, et al.*, – 21-cv-13325
2. *Estate of Sloan Mitchell v. Aurobindo, et al.*, – 21-cv-20355
3. *Kelly Donaldson v. Aurobindo Pharma, et al.*, – 21-cv-18272
4. *Charlene Mills v. Actavis, et al.* – 21-cv-13611
5. *James Larsen v. Actavis, et al.*, – 21-cv-18313
6. *Eric Thompson v. Aurobindo Pharma, et al.*, – 21-cv-19973
7. *Jimmie Thorn v. Mylan, et al.*, – 20-cv-20603
8. *Deborah Harris v. Aurobindo, et al.*, – 21-cv-6395
9. *Chadwick Wilson v. Aurobindo Pharma, et al.*, – 21-cv-20624

The issues in the *Byrnes*, *Mitchell*, and *Donaldson* matter are resolved, and those show cause orders may be withdrawn.

The issues in the *Mills*, *Larsen*, and *Thompson* matters remain unresolved, but the parties are working towards a resolution and request a one-month extension of these orders to show cause until the May 2022 Case Management Conference.

The issues in the *Thorn*, *Harris*, and *Wilson* matters remain unresolved and Defendants wish to proceed with dismissal of these three cases at the CMC.

b) Requested Show Cause Orders – Second Listing

Pursuant to CMO-16, the Plaintiff Fact Sheets in the below cases are substantially incomplete and contain core deficiencies. Each of these cases was previously listed on the agenda for a prior CMC. This list was provided to Plaintiffs' leadership on April 19, 2022, and a global meet and confer was held on April 25, 2022. Defendants have also been available for further discussion as needed. Accordingly, Defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next Case Management Conference, as to why these cases should not be dismissed.

Defense counsel will be prepared to address the individual issues with respect to each of these cases, to the extent necessary, during the April 29, 2022 Case Management Conference:

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c) First Listing Cases – Remaining Core Deficiencies:

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
1.	Michael Keicher v. Aurobindo Pharma, et. Al.	21-cv-20760	Honik LLC	Need medical expenses; need medical records	2/18/22
2.	Robert Sanford v. Aurobindo Pharma Ltd. et al.	21-cv-20674	Levin Papantonio Rafferty	Need medical expenses; amended PFS needs to be uploaded	3/2/22
3.	Carl Huston v. Aurobindo Pharma Ltd., et al	21-cv-20758	Honik LLC	-Failed to attach records demonstrating alleged injury	2/22/2022
4.	Ulysses Payne v. ZHP et al.	21-cv-00495	Serious Injury Law Group	-Failed to address numerous deficiencies listed in Deficiency Notice	3/8/2022
5.	Betty Hall v. Torrent	21-cv-20447	Serious Injury Law Group	No PFS Filed.	3/24/22
6.	Marion Dennis v. Solco	20-cv-11163	Serious Injury Law Group	No PFS Filed.	3/24/22

The following Plaintiff Fact Sheets contain core deficiencies that remain unresolved. This list was provided to Plaintiff leadership on April 19, 2022, and a global meet and confer was held on April 25, 2022. Defendants have also been available for further discussion as needed. This is the first time these cases have been listed on this agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
1.	Jerry Williams v. ZHP et al.	22-cv-00149	Hollis Law	Need medical expenses	3/24/22
2.	Tommy Benton v. Teva et al	21-cv-13858	Serious Injury Law Group	Largely deficient PFS	4/13/22
3.	Annie Pace v. Major Pharmaceuticals, et al	20-cv-19170	Serious Injury Law Group	Largely deficient PFS	4/13/22
4.	Rachel McDermott v. ZHP et al	21-cv-20426	Levin Papantonio	Need medical expenses	4/13/22
5.	Michael Shemes v. Aurobindo et al.	21-cv-20204	Law Offices of Sadaka Associates	No response to deficiency notice, including no records or authorizations uploaded and declaration not signed	3/14/22
6.	Curtis McCall v. Aurobindo et al.	21-cv-13859	Serious Injury Law Group	No response to deficiency notice, medications listed as “unknown”	3/28/22
7.	Mary Powell	21-cv-20436	Levin Papantonio	Amended PFS needs to be uploaded, missing medical expense records	3/29/22
8.	Michael Shapiro v. Aurobindo et al	21-cv-19906	Hollis Law Firm, P.A.	No medical records, no pharmacy records, no proof of use	3/2/22

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9.	Estate of Bernadine Badger v. Mylan Laboratories et al	20-cv- 08814	Parafinczuk Wolf, P.A.	No pharmacy records, no authorizations, deficient	3/19/22
10.	Mary Richards v. Mylan Laboratories et al	21-cv- 17150	Hollis Law Firm	Need Medical Expenses	3/19/22
11.	Gali Callahan	21 - CV- 20203	Law Offices of Sadaka Associates	Substantially deficient PFS, no authorizations, medical records, medical expenses, pharmacy records	3/22/22
12.	Margaret Tolley v. Mylan Laboratories et al	21-cv- 10130	DeGaris Wright McCall	Substantially deficient PFS, no authorizations, medical records, medical expenses, pharmacy records	3/21/22
13.	Katherine Peyton v. Mylan et al	21 - CV- 09063	DeGaris Wright McCall	Substantially deficient PFS, no authorizations, medical records, medical expenses, pharmacy records	3/21/22
14.	Gary Lee Tippet v. Aurobindo et al	22-cv-826	Pittman, Dutton & Hellums, P.C.	No PFS Filed	4/16/22
15.	Raymond Dais v. Aurobindo et al	22-cv-518	Dennis O'Brien PA	No PFS Filed	4/18/22
16.	Wayne Grubb v. Aurobindo et al	22-cv-918	Moore Law	No PFS Filed	4/22/22
17.	Christopher Gallagher v. Hetero et al	22-cv-930	Stark & Stark	No PFS Filed	4/22/22

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18.	Stacy Jackson v. ZHP et al	22-cv-1030	Levin Papantonio	No PFS Filed	4/25/22
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Respectfully Submitted,

A handwritten signature in black ink, appearing to read 'Jen', followed by a long horizontal line.

Jessica D. Miller

cc: All counsel of record (via ECF)